

**REMARKS**

Claims 1, 3 and 4 have been amended. Claim 2 has been canceled and its limitations have been incorporated in amended independent claim 1. Claims 1 and 3-8 are pending in this application.

Claims 1 and 3-8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Puddu (U.S. Patent No. 5,749,875) ("Puddu") in view of Betz et al. (U.S. Patent No. 6,287,308) ("Betz"). This rejection is respectfully traversed.

The claimed invention relates to a method of correcting bone deformities. As such, amended independent claim 1 recites a "method of correcting a deformity" by *inter alia* "resecting the bone . . . to leave a bony hinge on the second side," "opening the resection to a depth at which the deformity is corrected" and "placing the bone plate in a location such that the bone plate spans the open resection." Amended independent claim 1 also recites "packing the resection with prepackaged graft material provided in three sections, including two larger outer pieces and a smaller inner piece, by inserting the smaller inner piece behind the bone plate, and inserting the two larger outer pieces on either side of the smaller inner piece within the resection."

Puddu relates to a "system for performing proximal tibial or femoral osteotomies." (Abstract). Puddu teaches that "[T]he system includes a plurality of bone plates of various sizes, and a calibrated wedge tool for opening a resected tibial wedge and determining the size plate to use in the osteotomy." (Abstract). According to Puddu, once the forked wedge tool has been removed, "autologous bone is packed into the defect." (Col. 4, lines 38-39; Figure 9). Thus, "[I]f the gap in the corrected tibia is 7.5 mm or less, autograft bone is taken from tibia" or "[I]f the gap is wider than 7.5 mm, the bone graft is taken from the iliac crest." (Col. 4, lines 39-42; Figure 9).

Betz relates to a "method and apparatus for fusionless treatment of spinal deformities." (Title; Abstract). As part of the correction device 10 for the "treatment and

correction of spinal deformities, such as scoliosis,” Betz teaches “[M]echanical wedges (which) are engaged within the open wedge osteotomies on the concavity of the [spinal] curvature.” (Abstract; Col. 3, lines 66-67). Betz notes that “wedge member 43 . . . is configured to be disposed within the osteotomy site to maintain the positioning of the portions of the vertebral body after the osteotomy is opened.” (Col. 9, lines 29-32; Figure 3). Betz also teaches that the wedge member 43 of the connection device 40 “includes a wedge body 55 that is preferably fixed to the lower staple 41, such as by welding” and “a flat end face 58 that is aligned with the flat edge 47 of the lower staple 41.” (Col. 9, lines 36-38; lines 49-50; Figure 3).

The subject matter of claims 1 and 3-8 would not have been obvious over Puddu in view of Betz. Indeed, the Office Action fails to establish a *prima facie* case of obviousness. Courts have generally recognized that a showing of a *prima facie* case of obviousness necessitates three requirements: (i) some suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in the art, to modify the reference or combine the reference teachings; (ii) a reasonable expectation of success; and (iii) the prior art references must teach or suggest all claim limitations. See e.g., In re Dembiczak, 175 F.3d 994, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999); In re Rouffet, 149 F.3d 1350, 1355, 47 U.S.P.Q.2d 1453, 1456 (Fed. Cir. 1998); Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 U.S.P.Q.2d 1626, 1630 (Fed. Cir. 1996).

In the present case, Puddu and Betz, whether considered alone or in combination, fail to teach or suggest all limitations of claims 1 and 3-8. Puddu does not teach or suggest a “method of correcting a deformity” by *inter alia* “packing the resection with prepackaged graft material provided in *three sections, including two larger outer pieces and a smaller inner piece*,” as amended independent claim 1 recites (emphasis added). Puddu teaches only that “autologous bone is packed into the defect” subsequent to the removal of the forked wedge tool (col. 4, lines 38-39; Figure 9), and not that the bone material to be packed is “provided in three sections, including two larger outer pieces and a

smaller inner piece,” as in the claimed invention. Puddu is also silent about “inserting the smaller inner piece behind the bone plate, and inserting the two larger outer pieces on either side of the smaller inner piece within the resection,” as amended independent claim 1 also recites.

Similarly, Betz does not teach or suggest any of the limitations of claims 1 and 3-8. Betz does not teach or suggest a “method of correcting a deformity” by *inter alia* “resecting the bone . . . to leave a bony hinge,” much less “resecting the bone . . . to leave a bony hinge” and “opening the resection to a depth at which the deformity is corrected,” as amended independent claim 1 recites. Betz is also silent about “placing the bone plate in a location such that the bone plate spans the open resection,” as amended independent claim 1 also recites. As noted above, Betz relates to a surgical technique for correcting spinal deformities according to which “bone-piercing anchors” are employed to hold “the vertebral body on opposite sides of the body to retain the osteotomies on their desired orientations” so that wedge members could come in contact with the vertebral body. (Abstract).

Betz is also silent about “packing the resection with prepackaged graft material provided in three sections, including two larger outer pieces and a smaller inner piece,” much less about “inserting the smaller inner piece behind the bone plate, and inserting the two larger outer pieces on either side of the smaller inner piece within the resection,” as amended independent claim 1 recites. In Betz, the wedge member 43 and the wedge body 55 of the connection device 40 do not constitute “two larger outer pieces, and a smaller inner piece,” as the Examiner incorrectly asserts. (Office Action at 2). First, the wedge body 55 of Betz constitutes only one large piece, and not “two larger outer pieces,” as in the claimed invention. Second, Betz clearly notes that “the wedge member 43 includes a wedge body 55” and “a flat end face 58.” (Col. 9, lines 36-37; lines 49-50). Accordingly, the wedge member 43 of Betz could not be the “smaller inner pieces (43),” which would arguably correspond to the “smaller inner piece” of the claimed invention. Third, Betz does not teach or suggest the existence of any “smaller inner piece” as part of the

connection device 40, much less the existence of “two larger outer pieces and a smaller inner piece,” as recited in amended independent claim 1.

In addition, a person of ordinary skill in the art would not have been motivated to combine the teachings of Puddu with those of Betz because no suggestion or motivation to combine the references exists. Courts have generally held that, to establish a *prima facie* case of obviousness, “[I]t is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor.” Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934, 15 U.S.P.Q.2d 1321, 1323 (Fed. Cir. 1990). This way, “the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed.” Hartness Int’l, Inc. v. Simplimatic Engineering Co., 819 F.2d 1100, 1108, 2 U.S.P.Q.2d 1826, 1832 (Fed. Cir. 1987). Accordingly, a determination of obviousness “must involve more than indiscriminately combining prior art; a motivation or suggestion to combine must exist.” Pro-Mold & Tool Co., 75 F.3d at 1573.

As noted above, the crux of Puddu is a “system for performing proximal tibial or femoral osteotomies.” (Abstract). Puddu specifically teaches that “[T]he system includes a plurality of bone plates of various sizes, and a calibrated wedge tool for opening a resected tibial wedge and determining the size plate to use in the osteotomy.” (Abstract). On the other hand, the crux of Betz is the “treatment and correction of spinal deformities, such as scoliosis.” (Title; Abstract). Betz specifically emphasizes that “the addition of mechanical wedges into opening wedge osteotomies in the lumbar spine can be used to eliminate an abnormal lateral curvature while restoring the normal lordotic curvature of the lumbar vertebrae.” (Col. 4, lines 9-12). Accordingly, one skilled in the art would not have been motivated to combine Puddu, which teaches proximal tibial or femoral osteotomies, with Betz, which teaches wedge osteotomies in the spine. In addition, even if assuming *arguendo* that the two references would be combinable, there would be no motivation to combine the large wedge and bone plates of Puddu, for conducting tibial or femoral

procedures, with the small mechanical wedge of Betz, for conducting vertebral procedures. For at least these reasons, the subject matter of claims 1 and 3-8 would not have been obvious over Puddu in view of Betz, and withdrawal of the rejection of these claims is respectfully requested.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

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Respectfully submitted,

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**Version With Markings to Show Changes Made**

1. (Amended) A method of correcting a deformity by performing an osteotomy in a bone at an osteotomy site using a bone plate, the method comprising the steps of:

(a) resecting the bone from a first side of the bone to a second side of the bone so as to leave a bony hinge on the second side;

(b) opening the resection to a depth at which the deformity is corrected;

(c) placing the bone plate in a location such that the bone plate spans the open resection; and

(d) packing the resection with prepackaged graft material provided in three sections, including two larger outer pieces[,] and a smaller inner piece, by inserting the smaller inner piece behind the bone plate, and inserting the two larger outer pieces on either side of the smaller inner piece within the resection.

3. (Amended) The method of claim [2] 1, wherein the two larger outer pieces have outer surfaces formed of cortical bone.

4. (Amended) The method of claim [2] 1, wherein the step of inserting the smaller inner piece takes place prior to placing the bone plate.